IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Hikmat Hojeibane, et al.	
Serial No.	:	10/699,295	Art Unit: 3738
Filed	:	October 31, 2003	Examiner: Brian E. Pellegrino
For	:	IMPLANTABLE VALVULAR PROSTHESIS	

AMENDMENT and RESPONSE

Commissioner for Patents
PO Box 1450
Arlington VA 22313-1450

Dear Sir:

In response to the Office Action mailed on January 25, 2006 in the above-captioned patent application, please consider the following amendments and remarks.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims that begins on page 3 of this paper.

Remarks begin on page 10 of this paper.

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph under the heading ABSTRACT OF THE INVENTION with the following amended paragraph:

~~The present invention relates to a medical device, and in particular, to a stent-based valve.~~ ~~The~~ A prosthetic valve includes a radially expandable structural frame including an anchor structure having a first and a second open end, a connecting member having a first and a second end, and a cantilever valve strut having a first and a second end. The first end of the connecting member is attached to the second end of the anchor structure. The first end of the cantilever valve strut is cooperatively associated with the second end of the connecting member. The prosthetic valve further includes a biocompatible membrane assembly having a substantially tubular configuration about the longitudinal axis, with a first open and a second closed end. The first end of the membrane assembly is attached to the structural frame along the second end of the cantilever valve strut.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A prosthetic valve comprising:

a radially expandable structural frame defining a longitudinal axis, including an anchor structure having first and second open ends, a connecting member having first and second ends, the first end of the connecting member being rigidly attached to the second end of the anchor structure, and a cantilever valve strut having first and second ends, the first end of the cantilever valve strut being cooperatively associated with the second end of the connecting member and the second end of the cantilever valve strut being free to deflect in at least a radial direction from the longitudinal axis; and

a biocompatible membrane assembly having a substantially tubular configuration about the longitudinal axis, with a first open and a second closed end, the first end of the membrane assembly being attached along the second end of the cantilever valve strut.

2. (Original) The prosthetic valve of claim 1 wherein the anchor structure is formed from a lattice of interconnected elements, and has a substantially cylindrical configuration about the longitudinal axis.

3. (Original) The prosthetic valve of claim 1 wherein the structural frame comprises a material selected from the group consisting of stainless steel, tantalum, platinum alloys, niobium alloy, cobalt alloy, and nickel-titanium alloy.

4. (Original) The prosthetic valve of claim 1 wherein the structural frame comprises a polymer.

5. (Original) The prosthetic valve of claim 1 wherein the biocompatible membrane assembly is formed from a flexible membrane-like material.

6. (Original) The prosthetic valve of claim 5 wherein the membrane-like material is a biological material.

7. (Original) The prosthetic valve of claim 6 wherein the biological material is a vein.

8. (Original) The prosthetic valve of claim 5 wherein the membrane-like material is a synthetic material.

9. (Original) The prosthetic valve of claim 8 wherein the synthetic material is an elastomeric polymer.

10. (Original) The prosthetic valve of claim 8 wherein the synthetic material is a bioabsorbable material.

11. (Original) The prosthetic valve of claim 8 wherein the synthetic material further comprises a reinforcement fiber.

12. (Original) The prosthetic valve of claim 1 wherein at least a portion of the structural frame is coated with an agent.

13. (Original) The prosthetic valve of claim 12 wherein the agent coating contains a therapeutic agent.

14. (Original) The prosthetic valve of claim 12 wherein the agent coating contains a pharmaceutic agent.

15. (Original) The prosthetic valve of claim 12 wherein the agent coating comprises an agent-eluting layer.

16. (Original) The prosthetic valve of claim 1 wherein at least a portion of the membrane assembly is coated with an agent.

17. (Currently Amended) The prosthetic valve of claim ~~17~~ 16 wherein the agent coating contains a therapeutic agent.

18. (Original) The prosthetic valve of claim 17 wherein the agent coating contains a pharmaceutic agent.

19. (Original) The prosthetic valve of claim 17 wherein the agent coating comprising an agent-eluting layer.

20. (Original) The prosthetic valve of claim 1 wherein at least a portion of the membrane assembly is impregnated with a therapeutic agent.

21. (Original) The prosthetic valve of claim 1 wherein at least a portion of the membrane assembly is impregnated with a pharmaceutic agent.

22. (Original) The prosthetic valve of claim 1 wherein the connecting member is a substantially straight member oriented in a direction substantially parallel to the longitudinal axis.

23. (Withdrawn) The prosthetic valve of claim 1 wherein the connecting member has a substantially helical shape about the longitudinal axis.

24. (Original) The prosthetic valve of claim 1 wherein the cantilever valve strut is a substantially straight member oriented in a direction substantially parallel to the longitudinal axis.

25. (Withdrawn) The prosthetic valve of claim 1 wherein the cantilever valve strut has a substantially helical shape about the longitudinal axis.

26. (Withdrawn) The prosthetic valve of claim 1 wherein the cantilever valve strut has a substantially sinusoidal shape oriented in a direction substantially parallel to the longitudinal axis.

27. (Original) The prosthetic valve of claim 1 wherein the tubular biocompatible membrane has a substantially constant diameter from the first to the second end.

28. (Original) The prosthetic valve of claim 1 wherein the tubular biocompatible membrane has a substantially conical shape.

29. (Original) The prosthetic valve of claim 1 wherein the structural frame further comprising a proximal collar attached to the second end of the connecting member and first end of the cantilever valve strut.

30. (Withdrawn) The prosthetic valve of claim 29 wherein the structural frame further comprises a centering leg cooperatively associated with the proximal collar.

31. (Withdrawn) The prosthetic valve of claim 29 wherein the structural frame further comprises a proximal anchor cooperatively associated with the proximal collar.

32. (Currently Amended) A prosthetic valve comprising:

a radially expandable anchor structure formed from a lattice of interconnected elements, and having a substantially cylindrical configuration with a first and a second open end and a longitudinal axis defining a longitudinal direction extending there between;

a connecting member having a first and a second end, the first end of the connecting member being rigidly attached to the second end of the anchor;

a cantilever valve strut having a first and a second end, the first end of the cantilever valve strut being cooperatively associated with the second end of the connecting member, and the second end of the cantilever valve strut being free to deflect in at least a radial direction from the longitudinal axis; and

a biocompatible membrane assembly having a substantially tubular configuration with a first open and a second closed end, the first end of the membrane assembly being attached to the cantilever valve strut along the second end of the cantilever valve strut.

33. (Original) A prosthetic valve comprising:

a radially expandable anchor structure formed from a lattice of interconnected elements, and having a substantially cylindrical configuration with a first and a second open end and a longitudinal axis defining a longitudinal direction extending there between;

a collar located proximal to the radially expandable anchor;

a connecting member having a first and a second end, the first end of the connecting member being rigidly attached to the second end of the anchor and the second end of the connecting member being rigidly attached to the proximal collar;

a cantilever valve strut having a first and a second end, the first end of the cantilever valve strut being attached to the proximal collar and the second end of the cantilever valve strut being free to deflect in at least a radial direction from the longitudinal axis, the cantilever valve strut extending in a distal direction substantially parallel to the longitudinal axis ; and

a biocompatible membrane assembly having a substantially tubular configuration with a first open and a second closed end, the first end of the membrane assembly being attached to the cantilever valve strut along the second end of the cantilever valve strut.

REMARKS

In response to the Office Action mailed January 25, 2006, Applicants respectfully request that the Examiner reconsider the above-captioned application in view of the foregoing amendments, the following comments, and the Request for Continued Examination (RCE).

Objection to the Specification

The Examiner has objected to the specification, particularly the Abstract of the Invention, for including implied language. The Applicant's have amended the Abstract further to the Examiner's request and submit that the Abstract is now of proper language and format.

Objections to the Claims

The Examiner has objected to Claims 17-19 under 37 CFR 1.75(c), as being of improper dependent form. Applicants have amended Claim 17 to be in proper dependent form. Claims 18 and 19 depend from amended Claim 17 and thus are now also in proper form.

Rejection of Claims 1-5, 8, 9, 22, 24, 27-29, 32 and 33 under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1-5, 8, 9, 22, 24, 27-29, 32 and 33 under 35 U.S.C. § 102(e) as being anticipated by Huter et al. (6,511,496). The Examiner alleges that Figure 1 shows a prosthetic valve having an anchor structure (tubular stent) on a balloon, which is attached to a catheter device that has a collar 40 proximal to the anchor. The Examiner further alleges that the collar 40 is attached to a cantilever strut assembly 24 having a membrane assembly 22 attached thereto.

The Applicants respectfully assert that the Examiner has mischaracterized the structure cited in Huter et al., and that Huter et al. does not disclose all the elements claimed in Applicants' independent Claim 1.

Huter et al. Does Not Disclose a Valve with a Closed End

Claims 1, 32 and 33 of the present application disclose and claim a valve having a biocompatible membrane assembly. The membrane assembly has a substantially tubular configuration about the longitudinal axis, with first open and a second closed end. In the closed position, the valve is configured to substantially prohibit retrograde blood flow to pass through the valve.

Conversely, Huter discloses an embolic protection device or filter for capturing embolic particles entrained in blood flowing in an arterial vessel during interventional procedures. The filter includes an expandable strut assembly and a filtering medium. The filtering medium is formed from a thin elastic polymer membrane containing a plurality of holes, which allow blood to pass through the filter while capturing embolic particles. If the filtering medium did not allow blood to pass through it, it would not be able to filter embolic particles. See Abstract generally. Accordingly, Huter et al. Does Not Disclose a Valve with a Closed End.

Huter Does Not Have an Anchor Structure

Claims 1, 32 and 33 of the present application describe and claim an expandable structure, including an anchor structure having first and second open ends, and at least one

connecting member rigidly attached to the anchor structure. Claims 32 and 33 require the anchor structure to be formed from a lattice of interconnected elements. The first end of the connecting member is rigidly attached to the second end of the anchor structure. Claims 1 and 32 further claim that the second end of the connecting member is cooperatively associated with one end of a cantilever valve strut. Claim 33 claims a connecting member where the second end of the connecting member is attached to collar located. The Examiner alleges that Huter discloses an anchor structure (tubular stent) on a balloon, which is attached to a catheter device. However, the Examiner has not clearly pointed out what member in Figure 1 represents the anchor structure, and there is nothing in Huter disclosing an anchor structure on the balloon. Figure 1 depicts an angioplasty balloon back loaded over a guidewire. There is some kind of geometric shape on the balloon (represented but not identified in the figure), but is not described in the specification. The examiner seems to argue that this is an anchor structure (tubular stent) having first and second open ends as recited in Applicants' Claim 1. However, the Applicants respectfully assert that this could just as easily be ribbing or a textured surface on the balloon outer surface to prevent slipping across the lesion. The specification does mention a stent, which could arguably be construed as an anchor structure, but the specification states that once the balloon angioplasty procedure is complete, the balloon catheter 28 is removed and may be followed by a stent-delivery catheter (not shown) for placement of a stent across the dilated lesion. See col. 5, lines 57-61. This implies that dilation balloon does not have a stent over its outer surface. In addition, the specification specifically states that the stent-delivery catheter is not shown, intimating that the stent is not shown in the figures.

Huter Does Not Have an Anchor Structure Rigidly Attached to the Connecting Member

Assuming, *arguendo*, that Figure 1 does show a stent over the dilation balloon, the balloon/stent is not an anchor structure, and is not rigidly attached to a connecting member. In fact, the Examiner has not clearly articulated what he considers the connecting member. Instead, the Examiner has only stated what he believes to be akin to Applicants' anchor structure and cantilever valve strut (i.e. strut assembly 24).

The balloon and alleged stent in Huter is not an anchor structure and is not attached to a connecting member. Instead the balloon/stent in Huter is used to perform an angioplasty procedure and radially expanding or dilate artherosclerotic plaque. See col. 5, lines 45-57. The balloon 30 is attached to a balloon dilatation catheter 28 that is advanced over a guidewire. See col. 5, lines 45-55. The filter device containing the strut assembly 24 is rotatably mounted on the distal end of the guidewire. See col. 5, lines 37-38. Because the balloon catheter 28 is back loaded and advanced over the guidewire, the balloon 30 cannot be attached to any component of the filter device. It is clear that the balloon/stent assembly and filter device assembly are two complete and unattached devices free to slide over the guidewire 26 relative to one another.

Claims 1, 32 and 33 clearly require the anchor assembly to be rigidly attached to a first end of the connecting member, and a cantilever strut to be cooperatively associated or attached to the second end of the connecting member.

Huter Does Not Disclose a Connecting Member

As described above, Claims 1, 32 and 33 claim an expandable structure, including an anchor structure having first and second open ends, and at least one connecting member. The first end of the connecting member is attached to the second end of the anchor structure. Claim 33 further claims a collar located proximal to the radially expandable anchor, and a connecting member attached between the second of the anchor and the proximal collar.

The Examiner does not describe any component in Huter being a connecting member as claimed in independent Claim 1. The Examiner only describes a collar 40 in Huter, and alleges that collar 40 is attached to the catheter device, and the catheter device is attached to the balloon.

The strut assembly 24 of the filter device 20 includes an elongated cylindrical center portion 34 and proximal and distal end portions 36 and 38, terminating at proximal and distal, hollow, cylindrical guide wire collars 40 and 42. See col. 6, lines 7-12. Figure 3 clearly shows that the collar 40 is part of the strut assembly. As described above, the filter device containing the strut assembly 24 is rotatably secured to the distal end of the guidewire. See col. 5, lines 37-38. See also col. 8, lines 50-62. The balloon 30 is attached to the balloon dilatation catheter 28 that is advanced over the guidewire. See col. 5, lines 45-55. Because the balloon catheter 28 is back loaded and advanced over the guidewire (which is attached to the collar 40), the balloon 30 cannot be attached to any component of the filter device, including collar 40. Accordingly, Huter does not disclose a connecting member being attached to the second end of the anchor structure.

Huter Does Not Disclose Cantilever Valve Struts

Claims 1, 32 and 33 of the present application claim a cantilever valve strut having first and second ends, where the first end of the cantilever valve strut is cooperatively associated with the second end of the connecting member, and the second end of the cantilever valve strut is free to deflect at least radially from the longitudinal axis. The Examiner alleges that the cantilever valve strut assembly is expandable strut assembly 24.

The Applicants assert that the strut assembly 24 is not a cantilever valve strut. Instead, the strut assembly 24 in Huter is made up of individual struts 44. It is these struts 44 that are more appropriately akin to the cantilever valve struts claimed in the present application. However, it is clear from Figure 3 that the struts 44 in Huter are not cantilever valve struts as claimed by Applicants. Instead the struts 44 in Huter are fixed at both ends to collars 40 and 42. Even assuming that strut assembly 24 may be construed as a structurally equivalent member to the cantilever valve strut in Claims 1, 32 and 33, the strut assembly 24 is also not a cantilevered member. That is to say, the strut assembly 24 does not have an end that is capable of being free to deflect at least radially from the longitudinal axis.

A cantilever member is fixed on one end, having a second end that is free to deflect and move. The first end of the strut assembly 24 in Huter is attached to collar 40, but the second end is not free to deflect. Indeed the guidewire is slid through the second end of the strut assembly 24, restraining the second end and only allowing longitudinal movement of the strut assembly 24 relative to the guidewire. This arrangement is more akin to a beam fixed on one end by a pin,

while the second end is allowed to slide on a roller, which is not considered a cantilevered member.

Because Huter et al fails to disclose each of the elements recited by independent Claims 1, 32 and 33, Huter cannot anticipate Applicants' claimed device under 35 U.S.C. §102(e). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claim 1, 32 and 33 under 35 U.S.C. § 102(e) as being anticipated by Huter. As Claims 2-22, 24, and 27-29 depend directly or indirectly from independent Claim 1, Applicants similarly request that the Examiner withdraw the rejection to these claims under 35 U.S.C. § 102(b) as being anticipated by Huter. Further, Applicants assert that Claim 1 is an allowable generic claim linking Claims 23, 25, 26, 30 and 31. Accordingly, Applicants respectfully request the Examiner reinstate and allow these claims.

Rejection of Claim 11 under 35 U.S.C. § 103(a)

The Examiner rejected Claim11 under 35 U.S.C. § 103(a) as being unpatentable over Huter et al, in view of Konya et al. (6,368,338). The Examiner admits that Huter fails to disclose that the membrane material comprises a reinforcement fiber, but that Konya teaches that the filtering device can include reinforcement of structural fibers.

Konya does not Teach a Membrane Having Reinforcement Structural Fibers

The Applicants respectfully assert that the Examiner has mischaracterized the structure cited in Konya, and that Konya does not disclose a valve device, a filter device or a fiber reinforced membrane.

Konya discloses an occlusion device for occluding a vessel. The occlusion device comprises elastically deformable members 12 and a jacket 16. In the specification section cited by the examiner (col. 12, lines 23-31), polyester threads are used as an occluding agent 20 to facilitate quicker occlusion by providing more sites for thrombosis to occur. See also Figure 11. The polyester threads are not reinforcement fibers, and particularly not reinforcement fibers contained in a synthetic membrane used as a valve.

Conversely, the present invention clearly describes and claims a valve membrane having reinforcement fibers to further support the membrane.

Accordingly, Huter and Konya individually or in combination do not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Konya fails to teach all the claim limitations of dependent Claim 11. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 11 under 35 U.S.C. § 103(a).

There is no Teaching or Suggestion to Combine the References

A rejection under 35 U.S.C. § 103(a) requires that the Examiner make a factual showing that the claimed subject matter, as a whole, would have been obvious to a person of ordinary skill in the art. The combination of two or more references is only proper if there is some objective teaching in the prior art that would lead one of ordinary skill to combine the relevant

references. The references must be taken in their entiretics. It is impermissible within the framework of 35 U.S.C. § 103 to pick and choose from a reference only so much of it as will support a conclusion of obviousness. Accordingly, it is the Examiner's affirmative duty to show such a teaching in the art.

The Applicants respectfully assert that the Examiner has not met his burden under 35 U.S.C. § 103(a). The Examiner merely states that Konya teaches that the filtering device can include reinforcement or structural fibers, and that it would have been obvious to use reinforcement fibers as taught by Konya with the membrane of Huter such that is strengthens the apparatus and prevents collapse. The Examiner has not made an affirmative showing that the two references should be combined.

Huter discloses an embolic protection device or filter for capturing embolic particles entrained in blood flowing in an arterial vessel during interventional procedures. The filter includes an expandable strut assembly and a filtering medium. The filtering medium is formed from a thin elastic polymer membrane containing a plurality of holes that allow blood to pass through the filter while capturing embolic particles. See Abstract generally. Konya teaches an occlusion method and apparatus for creating a thrombus in a vessel for occlusion of the vessel. The devices each serve completely different functions, are different devices, and do not teach or suggest any combination of the two devices.

Applicants assert that Huter is not properly combinable with Konya for a rejection under 35 U.S.C. § 103(a). Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-5 and 7-10 under 35 U.S.C. § 103(a).

Rejection of Claims 6 and 7 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Quijano et al. (5,500,014). The Examiner asserts that Huter meets the claim limitations of Claim 1, but does not disclose that the use of biological vein material for the membrane.

As discussed above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Quijano fails to teach all the claim limitations of dependent Claims 6 and 7. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 6 and 7 under 35 U.S.C. § 103(a).

Rejection of Claims 10, and 12-21 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 10 and 12-21 under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Alt et al. (5,788,979). The Examiner asserts that Huter meets the claim limitations of Claim 1, but does not disclose that the structural frame or membrane is covered with a therapeutic agent. However, the Examiner asserts that Alt teaches that biodegradable polymer materials can be loaded with drugs or pharmaceutical agents.

As discussed above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Alt fails to teach all the claim limitations of dependent Claims 10 and 12-21. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 10 and 12-21 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully assert that the present application is now fully in condition for allowance, and such action is respectfully requested. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number listed below.

A Petition for a 1 Month Extension of Time, along with authorization to charge the petition fee to the Applicant's Deposit Account and a Request for Continued Examination (RCE), are being submitted with this Amendment and Response. No additional fee is thought to be necessary to enter this Amendment and Response. If an additional fee is required, the Examiner is authorized to charge the Applicants' Deposit Account - Account Number 10-0750/CRD-5051USNP.

Respectfully submitted,

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